

Biomarkers in breast cancer

59P

HEALTH ECONOMIC ANALYSIS OF GUIDELINE AND GENE EXPRESSION SIGNATURE-BASED RISK STRATIFICATION OF DISTANT RECURRENCE IN EARLY BREAST CANCER PATIENTS

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Introduction: In primary, estrogen receptor positive (ER+), HER2- breast cancer (BC), individual risk of distant recurrence determines if patients are recommended to undergo either adjuvant endocrine therapy alone or with additional chemotherapy (CT) to reduce the risk of recurrence. Clinical markers and molecular tests such as EndoPredict (EP, Sividon Diagnostics) can be used to support decision making for BC management.

Methods: Using a life-long Markov state transition model, we determined the health economic impact and incremental cost effectiveness ratios (ICERs) of applying the EP gene expression test in combination with three clinical guidelines (German-S3 [S3] 2008, NCCN 2007, St.Gallen [SG] 2011) to gain additional prognostic information in early ER+ HER2- BC patients. No CT or no test (all CT) served as reference strategies. Information on overall and metastasis-free survival were based on Austrian Breast & Colorectal Cancer Study Group studies (ABCSG6/8, n = 1619). Effectiveness was assessed in terms of quality-adjusted life-years (QALYs); a disutility for CT administration was included. Utilities and unit costs were derived from

published literature. Costs were assessed from the perspective of the German third-party payer. Costs and effects were discounted by 3%.

Results: The average life-long cost per patient ranged from EUR 25'910 (no CT) to EUR 35'997 (all CT). Due to imperfect prognostic value and differences in CT use, the various strategies led to clinical outcomes per patient ranging from 13.11 QALYs (no CT) to 13.17 QALYs (EP alone), respectively. The most favorable incremental cost-effectiveness ratio was achieved by applying EP to patients who were classified as high risk (luminal B) by SG, with EUR69'941/QALY compared to no CT. Compared to SG alone, the combined strategy with SG/EP would save EUR 3'225 (EUR 33'855 vs. EUR 30'088) and gain 0.005 QALYs per patient on average. The combination of guidelines with EP remained preferable in deterministic and scenario analyses.

Conclusion: Our model suggests that combining the SG guideline with EP is the most cost-effective approach in ER+ HER2- BC patients, from the perspective of the German health care system.

Disclosure: P.R. Blank: The research leading to these results has received funding from the European Community's Seventh Framework Programme (FP7/2007-2013) under grant agreement No 278659 and Sividon Diagnostics GmbH, Cologne, Germany. M. Schwenkglenks: The research leading to these results has received funding from the European Community's Seventh Framework Programme (FP7/2007-2013) under grant agreement No 278659 and Sividon Diagnostics GmbH, Cologne, Germany. P. Dubsy: PD has received honoraria from Sividon Diagnostics GmbH for lectures concerning Endopredict. M. Filipits: MF has received honoraria from Sividon Diagnostics GmbH for lectures concerning Endopredict. F. Gutzwiller: The research leading to these results has received funding from the European Community's Seventh Framework Programme (FP7/2007-2013) under grant agreement No 278659 and Sividon Diagnostics GmbH, Cologne, Germany. J. Brase: JCB is employee of Sividon Diagnostics GmbH R. Kronenwett: RK is employee and shareholder of Sividon Diagnostics GmbH.T.D. Szucs: The research leading to these results has received funding from the European Community's Seventh Framework Programme (FP7/2007-2013) under grant agreement No 278659 and Sividon Diagnostics GmbH, Cologne, Germany. All other authors have declared no conflicts of interest.